DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 21, 2014

Firstkind Limited
c/o Sheila Hemeon-Heyer, JD, RAC
Radcliffe Consulting, Inc.
231 Fairbanks Street
West Boylston, MA 01583

Re: K133638
Trade/Device Name: geko™ T-1 Neuromuscular Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: July 25, 2014
Received: July 25, 2014

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133638

Device Name
geko™ T-1 Neuromuscular Stimulator

Indications for Use *(Describe)*
The geko™ T-1 Neuromuscular Stimulator is intended for:
- Increasing local blood circulation, and
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.21 21:48:32 -04'00'

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

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HP13 7DL

Contact: Rachel Fallon
Chief Technology Officer

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B. Date Prepared: July 25, 2014

C. Device Name and Classification Information:

Trade Name:	geko™ T-1 Neuromuscular Stimulator (geko)
Common/usual Name:	Powered Muscle Stimulator
Classification Name:	Stimulator, Muscle, Powered
Product Code, CFR:	IPF, 21 CFR 890.5850
Panel code:	89
Class:	II

D. Predicate Device: SYS*STIM ME 208 (K031017)

E. Device Description:

The geko™ T-1 (geko™) Neuromuscular Stimulator is a disposable, fully integrated unit composed of a constant current pulse generator with embedded software and battery enclosed in an over-molded plastic casing, and a silver electrode with a hydrogel coating which provides a means of attachment of the device and electrical contact with the patient. A single button controls the On/Off function and the intensity level of the device, which is achieved through changes in the delivered pulse width. The geko™ is applied so that the electrodes lie over the common peroneal nerve behind

the knee. Stimulation of the common peroneal nerve causes contraction of the calf muscles through the direct activation of the motor neurons, resulting in increased blood flow.

The geko stimulus intensity varies with the pulse width, which can be set to one of seven levels to produce the appropriate muscle contraction within the patient comfort zone (70µs, 100µs, 140µs, 200µs, 280µs, 400µs, and 560µs). The asymmetric biphasic waveform results in a net charge of zero to the patient during each pulse cycle. The pulse rate is fixed at a frequency of 1 Hz and is used to isometrically stimulate the leg and foot muscles with a cadence and energy similar to that of walking.

Electrical contact is made with the patient through a hydrogel layer applied during manufacture to the integrated electrode. The patient contacting materials have been tested per the requirements of ISO 10993-1 and shown to be biocompatible for prolonged (up to 30 days) contact with intact skin. There are no separate electrode leads or electrodes.

F. Indications for Use:

The geko™ T-1 device is a Neuromuscular Stimulator and is intended for:

- Increasing local blood circulation, and
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis.

G. Contraindications

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Powered muscle stimulators should not be used on patients with recently diagnosed deep vein thrombosis.

H. Technical Comparison with the Predicate Device and Discussion of Differences

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Intended Use and Indications for Use	The geko T-1 is a neuromuscular stimulation device and is intended for: • Increasing local blood circulation • Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis	1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post-surgical pain 2. Temporary relation of muscle spasm **3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles** **4. Increasing local blood circulation** 5. Prevention or retardation of disuse atrophy 6. Muscle re-education 7. Maintaining or increasing range of motion	The indications for use of the geko™ T-1 are a subset of the indications for use of the predicate device (see #3 and #4 for the SYS*STIM 208)
Clinical application	Prescription use only for use in a clinical or home use setting. Single patient use for up to 30 hours (replacement recommended after 24 hours)	Prescription use only for use in a clinical or home use setting. The device is reusable but the electrodes are single use, disposable.	Substantially equivalent. Both devices are for prescription use in a clinical or home environment.
Anatomical Sites	The electrodes are applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	Electrodes can be applied to multiple anatomical sites, including the posterior aspect of the knee only for stimulation of the peroneal nerve.	Substantially equivalent. Both devices can be used for stimulation of the peroneal nerve.

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Basic Unit Characteristics			
Power source **-Method of Line Current Isolation**	One CR2032 primary lithium coin cell. Not replaceable by user N/A	Mains (line) voltage Transformer isolation	Substantially equivalent. Both devices meet electrical safety standards.
-Patient Leakage Current **-Normal Condition** **-Single Fault Condition**	< 20µA < 20µA	<100 µA <300 µA	Substantially equivalent. Leakage current of geko is less than predicate device.
Number of output modes	Single mode with seven discrete stimulation settings corresponding to the seven pulse widths.	Three output modes The “Pulse” mode has a 200 µs pulse width	Substantially equivalent to “Pulse” mode of predicate.
Number of output channels	Single channel	Single channel	Same
-Synchronous or alternating	N/A (single channel)	N/A (single channel)	Same
-Method of channel isolation	Capacitor	Transformer	Substantially equivalent. Both methods are effective methods of channel isolation.
Regulated current or regulated voltage	Current regulated	Voltage regulated	Substantially equivalent. Both methods comply with electrical safety standards.
Microprocessor controlled?	Yes	Yes	Same

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Automatic overload trip	Yes	No	Substantially equivalent or better.
Automatic no-load trip	Yes	No	Substantially equivalent or better.
Automatic shut-off	Yes	Yes	Same
Patient over-ride control	Yes	Yes	Same
Indicator display			
- On/Off status	Yes	Yes	Same
- Low battery	Yes (device switches off)	N/A	Substantially equivalent
-Voltage / current level	N/A (device has fixed constant current)	Yes (intensity control)	Substantially equivalent.
-Charge level (pulse width)	Yes (pulse width varies to change delivered charge), The stimulation level (pulse width) is indicated by the flashing of the LED The number of times LED flashes in sequence indicates the level of stimulation, with level 1 (a single flash) equating to 70 µs being the lowest stimulation level and level 7 (7 flashes in sequence) equating to 560 µs, the highest. stimulation level	N/A (device has fixed pulse width (200 µs)).	Substantially equivalent.
Timer range in minutes	1800 minutes maximum (device is disabled after 30 hours battery run time)	60 minute timer can be reset indefinitely	Substantially equivalent.

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Compliance with voluntary standards	Yes IEC 60601-1:1998 A1, A2 IEC 60601-2-10:1987, A1 EN 60601-1-2:2007 ISO 10993-1	Yes UL 2601-1 CAN/CSA-22.601.2.10-92	Substantially equivalent
Compliance with 21 CFR 898	N/A (electrodes are integral with the device, there are no separate leads)	Yes	Substantially equivalent
Weight	18 g	1.4 pounds (636g)	Substantially equivalent. Both devices are small and lightweight.
Dimensions	6” x 1.6” x 0.43”	2.75” x 6.1” x 8”	Substantially equivalent
Housing material and construction	Plastic injection molding	Plastic injection molding	Substantially equivalent
Output Specifications			
Waveform **-Pulsed monophasic or biphasic** **- Shape**	 Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	 Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	 Same Same
Maximum output voltage	13.5 V @ 500 Ω 54 V @ 2000 Ω 110 V @ 10,000 Ω	92 V @ 500 Ω (measured) 144 V @ 2000 Ω 166 V @ 10,000 Ω	Substantially equivalent. Geko can operate at lower voltage as intensity is increased by increasing pulse width.
Maximum output current	27 mA @ 500 Ω 27 mA @2000 Ω 11 mA @ 10,000 Ω	184 mA @ 500 Ω 72 mA @2000 Ω 17 mA @ 10,000 Ω	Substantially equivalent for same reason as above.

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Pulse width	70, 100, 140, 200, 280, 400, 560 µs	200 µs	Substantially equivalent. Predicate varies intensity by increasing voltage/current in fixed pulse width.
Frequency	1 Hz	1 to 80 Hz	Substantially equivalent. Low frequency used to increase circulation.
For interferential modes only: **-beat Frequency (Hz)**	N/A	N/A	Same
Multiphasic waveforms **-Symmetrical phases**	No	No	Same
-Phase duration	70-560 µs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant.	200 µs	Substantially equivalent. Reasons previously discussed.
Net charge **-How achieved**	0 µC at 500 Ω Capacitor coupling	~0 µC at 100 Ω Transformer coupling	Same Methods are substantially equivalent.
Maximum phase charge	18.3 µC at 500 Ω	33.5 µC at 500 Ω	Substantially equivalent or better
Maximum current density	6.67 mA/cm^2	9.12 mA/cm^2	Substantially equivalent or better.
Maximum power density	0.000044 W/cm^2	0.012 W/cm^2	Substantially equivalent or better.

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Burst mode **a) Pulses per burst** **b) Bursts per second** **c) Burst duration (seconds)** **d) Duty Cycle [Line (b) x Line (c)]**	N/A (single pulse, no pulse train or burst)	N/A when used in PULSE mode (single pulse)	Same.
ON Time (seconds)	N/A Stimulation is delivered at 1 Hz, with single pulses of 70µs to 560µs	N/A Stimulation is delivered at 1 Hz, with single pulses of 200 µs	Same.
OFF Time (seconds)	N/A Stimulation is delivered at 1 Hz, with single pulses of 70µs to 560µs	N/A Stimulation is delivered at 1 Hz, with single pulses of 200 µs	Same.
Additional Features			
Indicators			
- On/Off status	Yes	Yes	Same
- Low battery	Yes (device switches off)	N/A (mains powered)	Substantially equivalent
-Voltage / current level	Yes. Fixed constant current (pulse width varies to change delivered charge)	Yes Continuously variable using un-calibrated dial	Substantially equivalent
-Low stim current	Yes. Unit turns off after 4 minutes below low current threshold	No	Substantially equivalent or better
-High stim current	Yes. Unit turns off immediately	No	Substantially equivalent or better

Parameter	geko™ T-1	SYS*STIM ME 208 (K031017)	Substantial Equivalence
Electrodes	Hydrogel applied to silver electrode. Biocompatibility for the hydrogel has been established.	Conductive adhesive gel	Substantially equivalent. Both comply with FDA recognized standards.
Cables/ connectors	Integrated device: no separate cables	Separate cables, assembled by user	Substantially equivalent or better.
Patient-contact	Contact is made through integrated self-adhesive electrodes. The geko™ T-1 is a single channel device.	Contact is made through adhesive electrodes. The SYS*STIM ME 208 is a single channel device	Substantially equivalent

I. Nonclinical Data:

The following nonclinical testing was provided in this 510(k):

Shelf Life Testing – Real-time shelf life testing was conducted. Devices in their final packaging were stored under controlled conditions at 30°C for 27 months then subjected to full technical performance testing following 24 hours of operation. The results of this testing confirmed that the device remains fully operational in accordance with its performance specifications after 27 months of aging, and support a labelled shelf life of 24 months.

Biocompatibility Testing – The patient contacting materials of the device (hydrogel and adhesive strip) were subjected to biocompatibility testing per ISO 10993-1:2009, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing,” for devices in contact with intact skin, including cytotoxicity, dermal sensitization, and dermal irritation. In view of the potential for repeated sequential use of the device, repeat dermal irritation testing of the hydrogel was also conducted. All tests passed.

Software Verification and Validation – Software documentation consistent with a moderate level of concern was submitted in this 510(k). Latent software design flaws or faults would not be expected to result in user or patient injury. System validation testing presented in this 510(k)

demonstrated that all software requirement specifications were met and all software hazards were mitigated to risk level 1 (Accept).

Electrical Safety and Electromagnetic Compatibility Testing – The geko™ T-1 has been certified by Intertek to comply with the applicable clauses of the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; +A1:1991-11, +A2, 1995
- IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators; 1987; +A1 2001
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 3rd edition, 2007.

Engineering Bench Testing – In addition to the full system validation testing, the 510(k) also included testing in accordance with the recommendations of FDA's Guidance Document for Powered Muscle Stimulator 510(k)s, Attachment II, Section 1 – Output Waveforms. Oscilloscope tracings were obtained of the device output waveforms at each pulse width (i.e., intensity settings 1 through 7) under loads of 500Ω, 2 kΩ and 10kΩ. These tracings demonstrated that the net charge in the geko output waveform at all settings is 0.

J. Clinical Data

The safety and effectiveness of the geko™ T-1 has been evaluated in independent clinical studies. The work of Tucker et al.[1] established that a 1 Hz frequency electrical stimulus applied at the common peroneal nerve resulted in significant increases ($p<0.01$) in venous volume flow, blood flow velocity, and microcirculatory flux in the stimulated leg as compared to the non-stimulated control leg. The changes in blood flow parameters were comparable amongst all stimulus frequencies (1 Hz to 5Hz); however, the highest amplitude/frequency programs reached a moderate discomfort level on the subject verbal rating scale, while the lowest frequency of 1 Hz was well

[1] Tucker AT, Maass A, Bain DS, Chen L, Azzam M, Dawson H, Johnston A. Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. *Int J Angiol* 2010; Spring 19(1): e31-7.

tolerated by all subjects. This work formed the basis for developing the geko™ T-1 device.

Subsequently, three independent investigations studied the safety and efficacy of the geko™ T-1: two in healthy subjects and one in patients undergoing elective unilateral total hip replacement. Warwick et al.[2] applied the geko™ T-1 to the common peroneal nerve of 10 healthy volunteers, setting the simulation level to elicit a palpable twitch of the foot, according to the manufacturer's instructions. Assessments of blood flow velocity, volume and average velocity using Doppler ultrasound, and vessel diameter using ultrasound imaging were made with the subjects in four positions: 1) lying supine, lower limb horizontal; 2) supine, lower limb elevated at 25 to 35 degrees hip flexion; 3) standing, non weight-bearing (weight on contralateral leg only); and 4) standing, weight-bearing (weight evenly distributed on both legs). Assessments were made after 10 minutes in each position with the geko™ T-1 turned off, then repeated in each position during active stimulation. A plaster cast was then applied to the lower limb of each subject, and the assessments were repeated, first with the geko™ T-1 inactive and then with the device active.

In all postural positions, both with and without the plaster cast, peak venous velocity was significantly higher ($p<0.05$) when the geko™ was active. There were no significant effects on blood flow due to the presence of the plaster cast or change in postural position for the active geko™ measurements. The median discomfort rating for all positions while the geko™ was active was 2, corresponding to "minimal discomfort."

Jawad et al.[3] compared the effectiveness of neuromuscular electrostimulation using the geko™ to two commercially available intermittent pneumatic compression (IPC) devices in 10 healthy volunteers. Measurements of lower leg blood flow, blood volume, and microcirculatory velocity were taken after 30 minutes of supine rest and then following 30 minutes of active application of each device type applied bilaterally in a predefined randomized pattern. The geko™ T-1 was applied at both the

[2] Warwick D, Shaikh A, Gadola S, Stokes M, Worsley P, Bain D, Tucker A, Gadola SD: Neuromuscular electrostimulation via the common peroneal nerve promotes lower limb flow in a below-knee cast: a potential thromboprophylaxis. *Bone Joint Res*, Sep 2013, 2(9):179-85.
[3] Jawad H, Bain DS, Dawson H, Crawford K. A comparative study investigating the effectiveness of neuromuscular electrostimulation versus intermittent pneumatic compression in enhancing lower limb blood flow in healthy subjects. Submitted for publication to *J Thrombosis and Haemostasis.*

subject's threshold level for muscle twitch and a setting three levels above the threshold.

The authors reported that neuromuscular stimulation using the geko™ T-1 resulted in significantly higher ($p<0.001$) venous and arterial blood volume flow measures and microcirculatory blood velocity at both settings as compared to both of the IPC devices. There were no safety concerns reported for any of the devices used. Subject perception ratings evaluated using a visual analog scale (VAS) and a verbal rating scale (VRS) ranged from "minimal sensation" to "mild discomfort." The authors concluded that the geko™ T-1 was superior to the IPC devices in enhancing blood flow in the lower limbs, even when used at the subject's threshold setting.

The geko™ T-1 device was also studied in a group of 40 patients undergoing elective unilateral total hip replacement (THR) who were randomized to receive post-surgical DVT prophylaxis treatment with either the geko™ T-1 or Thromboembolism Deterrent Stockings (TEDS).[4] The intervention was worn from immediately post-surgery to hospital discharge, which was 4 days for most subjects (the geko™ T-1 was changed every 24 hours). The study results demonstrated that: 1) use of the geko™ T-1 significantly increased venous blood velocity as compared to no treatment; and 2) the blood flow increase seen in the geko™ group was greater than in the TEDS group. There were no device-related adverse events reported in this study. Given that the performance of prophylactic interventions for DVT is conventionally measured in terms of venous flow augmentation, this study demonstrated that the geko T-1 is both safe and effective for use in post-surgical prevention of DVT.

I. Conclusions

The information and testing presented in this 510(k) demonstrated that that the geko™ T-1 performs as designed and intended and is substantially equivalent to the predicate device, the SYS*STIM ME 208, for the indications of neuromuscular stimulation of the peroneal nerve to increase local circulation and for immediate post-surgical prevention of DVT.

[4] Unpublished study conducted at the Harbour Hospital in Poole, Dorset, UK.